silhouette®
wound + skin assessment

aranzmedical

Proving Efficacy and Safety for Promore Pharma

PROMORE PHARMA
leading-edge medical innovation

Sponsor: Promore Pharma AB (publ).

Location: 18 sites across Sweden and Poland.

Study Title: A Study in Patients with Hard-to-Heal (HTH) Venous Leg Ulcers (VLUs) to Measure Efficacy and Safety of Locally Administered LL-37 (ropocamptide).

Primary Objective: To determine the efficacy of ropocamptide, at concentrations of 0.5 and 1.6 mg/mL, in increasing the incidence of complete wound closure compared with placebo in the treatment of HTH VLUs.

Secondary Objectives: To determine the efficacy of ropocamptide, at concentrations of 0.5 and 1.6 mg/mL, in promoting wound healing in relation to secondary efficacy endpoints, as well as to evaluate local tolerability and safety of ropocamptide, compared with placebo in the treatment of HTH VLUs.

Timeframe: a 13 week treatment period and a 16 week followup period.

Phase: IIb.

Allocation: Randomized.

Endpoint Classification: Safety/Efficacy Study.

Intervention Model: Parallel Assignment.

Masking: Double-blind.

In 2018, Promore Pharma undertook a multi-site, randomized, phase IIb trial to further prove the efficacy and safety of ropocamptide (LL-37) for patients with hard to heal (HTH) venous leg ulcers (VLUs).

This study followed on from a previous clinical study in which ropocamptide was administered to patients with HTH VLUs. The original study demonstrated a statistically significant early healing response with twice-weekly applications of ropocamptide and no safety concerns.

The active substance used in these studies, ropocamptide, is a synthetic peptide with an amino acid sequence identical to the human endogenous wound healing peptide LL-37. The study hypothesized that local supplementation of biologically relevant concentrations of synthetic ropocamptide on HTH VLUs would promote wound healing.

To reduce the risk of bias in the study outcomes, the treatment allocation was blinded to both staff and patients and it was not possible to distinguish the active drug from the placebo.

Documenting the Study

At each of the 18 study sites, photographs and area measurements of the ulcers were gathered using the SilhouetteLite+ application installed on iPads. SilhouetteLite+ automatically calculates the ulcer area from the boundary tracing of the ulcer on the image. Once each subject's assessment was complete,

the images and data collected at the trial sites were automatically uploaded to the secure central database, SilhouetteCentral, hosted on Microsoft's cloud computing service, Azure.

In order to ensure the assessment data collected at the sites was not subject to any bias, Promore Pharma also utilized ARANZ Medical's data quality control, data management and independent assessor services.

Data Quality Control

The data quality services ensured that the data collected at each of the sites was recorded consistently and accurately throughout the study. Any duplicates or errors identified through the quality control process were remedied periodically throughout the study.

Independent Assessor Review

Promore Pharma also requested to have their data independently assessed during the study to ensure the data they had collected was not biased. Twice during this study, ARANZ Medical cloned copies of the wound assessments and notes for the independent assessor's review. Once the data had been assessed it was transferred back to Promore Pharma.

Why Silhouette?

Promore Pharma chose Silhouette for a number of reasons. Chief Scientific Officer, Prof. Margit Mahlapuu says: ***"At each site we had the SilhouetteLite+ app on iPads, which enabled all of the different clinicians to easily gather the images and data in exactly the same way. It was crucial in this study to have the data collected in reliable, consistent ways from all the sites and all of the different clinicians who were doing the assessments, and Silhouette enabled us to do that.***

The ability to have the data checked and validated by an independent assessor was also key to our decision. This study was designed to address whether ropocamptide improves VLU healing rates and there was no room for any errors in the way we gathered or reported the data. The ARANZ Medical team were great to work with and the Silhouette system was easy to use and provided accurate information - both of these elements played important roles in the success of this study."

The image below shows a dashboard view of the SilhouetteCentral database displaying healing data.

The image above shows an iPad with the SilhouetteLite+ sensor attached, enabling non-contact 2D measurements.

The Results

The results are planned for announcement in Q4, 2020.

About Promore Pharma

Promore Pharma is a biopharmaceutical company specialized in the development of therapeutic peptides. The company's aim is to develop first-in-category pharmaceuticals for indications where very few efficacious prescription pharmaceuticals are available, thus, addressing high unmet medical needs. The company is listed on Nasdaq First North Growth Market. For more information visit: www.promorepharma.com.

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